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10/098,683	03/15/2002	Gary Karlin Michelson	101.0042-05000	7210

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/098,683	MICHELSON, GARY KARLIN	
	Examiner	Art Unit	
	Melanie Tyson	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-65,67-90 and 92-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-65,67-90 and 92-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/07 & 1/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicant's amendment received on 19 December 2007.

Specification

1. The amendment filed 18 June 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In one embodiment, the bone growth promoting material includes a liquid fusion promoting material and a solid fusion promoting material other than bone provided in at least one portion of the hollow interior to promote growth from adjacent vertebral body to adjacent vertebral body through the implant (refer to amended abstract). Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-65, 67-78, and 104-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant failed to disclose a liquid fusion promoting material and a solid fusion promoting material at the

time the application was filed (see claims 54, 67, and 104-106). Applicant simply disclosed bone fusion promoting material, such as hydroxyapatite, tricalcium phosphate, and bone morphogenetic protein. Therefore, claims 54-65, 67-78, and 104-106 contain new matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 54-65, 67-90, and 92-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray et al. (5,026,373).

Ray discloses a spinal fusion implant comprising upper and lower surfaces having openings there through, a hollow interior for holding bone graft or bone growth promoting material, an insert end and a trailing end having a rear wall (fig. 1 and 5) and the implant being made from the material as claimed. Ray also discloses the hollow interior having an interior surface with a total surface area about 75% (inherently) and

25% of area perforated (cols. 9-10). Although Ray does not disclose bone growth promoting material being bone morphogenetic protein, hydroxyapatite, hydroxyapatite tricalcium phosphate, or a combination thereof (wherein these materials are inherently bioactive and/or bioresorbable materials), the bone growth promoting materials as claimed are well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the bone growth promoting materials as claimed in Ray's implant in order to promote new bone growth, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Regarding the bone growth promoting material, it also would have been obvious matter of design choice to employ more than one bone growth promoting material in the Ray implant, since applicant has not disclosed that having two different growth promoting materials would solve a stated problem or is used for any particular purpose, and it appears that the implant would perform equally well with one or more promoting materials.

Regarding coating a bone implant, coating a bone implant with the bone growth promoting material is also well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the Ray implant with bone growth promoting material in order to provide a better surface for new bone to growth into the implant and forming bone fusion.

Response to Arguments

6. Applicant's arguments filed 19 December 2007 have been fully considered but they are not persuasive. Applicant argues primarily that at the time the application was filed, liquid fusion promoting materials and solid fusion promoting materials were disclosed, and it would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ray's device as claimed. Examiner respectfully disagrees.

Applicant argues that, as used in bone fusion, the solid states of hydroxyapatite and hydroxyapatite tricalcium phosphate, and the liquid state of BMP are inherent properties of these materials, therefore, liquid fusion promoting materials and a solid fusion promoting materials were disclosed. However, the terms "liquid" and "solid" cover other materials in addition to those disclosed by the applicant. Although the materials disclosed by the applicant may inherently contain these properties, the applicant did not disclose all liquid and solid fusion promoting materials. Applicant simply disclosed hydroxyapatite, hydroxyapatite tricalcium phosphate, BMP, or a combination thereof. Therefore, the objection and rejection stands.

Applicant further argues that as of the priority date of the present application it would not have been obvious to one of ordinary skill in the art to use liquid and solid fusion promoting materials as recited in independent claims 54 and 79. As stated in the previous office action, coating bone implants with bone growth promoting materials is well known in the art. Furthermore, materials such as BMP, hydroxyapatite, and hydroxyapatite tricalcium phosphate are well known in the art. For example, prior art

Rueger et al. (5,344,654) teach coating a prosthesis or implant with materials such as hydroxyapatite and hydroxyapatite tricalcium phosphate for enhancing bone growth and fixation (for example, see column 11, lines 2-10). Prior art Pillar et al. (5,344,457) teaches coating implants with materials such as BMP and hydroxyapatite to enhance bone growth (for example, see column 8, lines 10-24). Since the prior art provides evidence that implants combined with liquid or solid materials, or bioactive or bioresorbable materials, are well known in the art, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the bone growth promoting materials as claimed in Ray's implant in order to promote bone growth and enhance fixation. Furthermore, it would have been an obvious matter of design choice to employ more than one bone growth promoting material in the Ray implant, since applicant has not disclosed that having two different growth promoting materials would solve a stated problem or is used for any particular purpose and it appears that the implant would perform equally well with one growth promoting material.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
February 29, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773